Original Research

Cabergoline for Lactation Inhibition After Early Second-Trimester Abortion or Pregnancy Loss

A Randomized Controlled Trial

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OBJECTIVE: To evaluate cabergoline's efficacy at decreasing lactation symptoms after early second-trimester abortion or pregnancy loss.

METHODS: This is a multisite, double-blind, gestational-age stratified superiority trial that compared cabergoline 1 mg once with placebo for preventing bothersome breast symptoms immediately after uterine evacuation. We enrolled pregnant people at 16–20 weeks of gestation who were English- or Spanish-speaking and without contraindication to the study drug. Participants received cabergoline within 4 hours of uterine evacuation or fetal expulsion and, at baseline and at multiple time points through 2 weeks postprocedure, completed a validated electronic survey that assessed breast symptoms, side effects, and bother. Our primary outcome was breast symptoms (a composite of engorgement, milk leakage, tenderness, and need for pain relief) on day 4; we planned to enroll 30 participants in each gestational duration strata to show a 40% difference in breast symptoms (80% power, α=0.049).

RESULTS: After screening 145 patients from February 2024 through May 2025, we enrolled 69 eligible participants. Baseline demographics were balanced between groups: Median gestational duration was 18 weeks (range 16 0/7–19 6/7 weeks), 53.0% were nulliparous, 63.6% self-identified as Hispanic, and 68.2% had public insurance. On day 4, significantly fewer participants who received cabergoline reported any breast symptoms compared with placebo (50.0% vs 88.2%, $P<.001$) (primary outcome) and fewer participants reported significant bother from breast symptoms (3.1% vs 20.6%, $P=.05$) (secondary outcome). These differences persist even in the earlier gestational duration strata.

CONCLUSION: Cabergoline is an effective and well-tolerated medication to prevent breast symptoms after early second-trimester abortion or pregnancy loss.

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Lactogenesis is a two-stage physiologic process that results in the ability to secrete milk, starting in the 16th week of pregnancy and continuing after delivery regardless of the birth outcome.[1,2] Breast pain after second-trimester abortion or pregnancy loss is common[3] and can cause emotional distress.[4]

Dopamine agonists, such as cabergoline, are safe and effective in lactation inhibition for third-trimester fetal death or neonatal loss and for patients with contraindications to breastfeeding.[5] Cabergoline is U.S. Food and Drug Administration–approved for the treatment of hyperprolactinemic disorders, either idiopathic or due to pituitary adenomas (https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/020664s016lbl.pdf).

In a cross-sectional survey of reproductive health care clinicians, significant practice variation was identified in counseling and management of breast engorgement after second-trimester abortion or pregnancy loss.[6] Our prior clinical trial found that, among patients seeking abortion care or management of fetal death at 18–28 weeks of gestation, significantly fewer people who received a single dose of cabergoline 1 mg after uterine evacuation reported any breast symptoms compared with those who received the placebo.[7] Given these findings, joint guidelines from the Society of Family Planning and Society for Maternal-Fetal Medicine recommend offering cabergoline to individuals at 18–28 weeks of gestation who are undergoing induction or dilation and evacuation.[8]

Nationally, less than 1% of abortion care occurs beyond 16 weeks of gestation; most outpatient clinics provide abortion care before 20 weeks. We were underpowered in our original study to draw conclusions about individuals at 18–20 weeks of gestation, and individuals at 16–18 weeks were excluded.[7] Because there is biological plausibility that lactogenesis starts as early as 16 weeks of gestation,[1,2] this follow-up study sought to determine whether cabergoline is beneficial earlier in the second trimester.

METHODS

We conducted a multisite, double-blind, placebo-controlled, gestational-duration stratified superiority trial from February 2024 through May 2025 to evaluate off-label use of cabergoline in preventing breast engorgement after early second-trimester abortion or fetal death. We received approval from the Stanford University IRB (IRB No. 80200), registered on ClinicalTrials.gov (NCT06029673), and obtained a National Institutes of Health Certificate of Confidentiality (CC-OD-23-5049) before recruitment. This study was designed and reported using CONSORT (Consolidated Standards of Reporting Trials) guidelines.[9]

We recruited English- or Spanish-speaking pregnant participants aged 18 years or older who were between 16 0/7 and 19 6/7 weeks of gestation and were consented for abortion or management of fetal death at Stanford Gynecology or Planned Parenthood Mar Monte. We excluded patients with prior mastectomy, those currently breastfeeding, those currently receiving a dopamine agonist or antagonist, or those with a contraindication to cabergoline per package insert. Participants were compensated for their time based on number of surveys returned.

Standard patient-centered counseling regarding medical or surgical management for abortion care or management of fetal death was provided. A complete history was obtained and physical examination performed by the treating clinician. For patients with an ongoing pregnancy, gestational duration on the day of the procedure was determined by the treating clinician based on last menstrual period and correlation to earliest available ultrasonogram.[10] Gestational duration for patients with fetal death was determined by biometry.[11] Participation in the trial did not affect standard clinical care such as cervical preparation or induction regimen, the setting of clinical care (inpatient or outpatient), antibiotic prophylaxis, Rh-immune globulin administration, or fetal disposition or testing.

A research coordinator obtained informed consent and randomized the participant based on gestational-age strata to cabergoline or placebo before the procedure. Randomization was performed using variable block sizes of 4 and 8, stratified by study site and gestational duration. Participants, clinicians, and clinical researchers at both recruitment sites remained blinded to allocation until data analysis occurred. Basic demographic information was collected and entered into REDCap by a research coordinator.[12] Standard questions regarding demographics such as self-identified gender identity and race and ethnicity, prior breastfeeding or chestfeeding experience, and prior breast surgery were asked of participants. Race was collected to assess potential differences in treatment response and ensure the study's findings are generalizable across diverse populations. Participants completed a baseline survey to establish existing breast symptoms and bother.

The clinical research coordinator distributed cabergoline 1 mg or placebo (identical sugar tablets) to the participant within 4 hours of the procedure or fetal expulsion. All participants received written

instructions to wear a support bra and apply ice packs, as needed, after the procedure.

Online surveys were collected at enrollment (baseline) and on days 2, 4, 7, and 14 after the procedure. Additionally, we asked participants on day 14 to rate overall satisfaction with the pharmacologic intervention. RedCap automatically sent surveys to participants at 8:00 AM on the specified day. A clinical research coordinator made a phone call to the participant in the evening if the survey was not completed that day.

Based on prior input from breastfeeding medicine specialists, a complete absence of symptoms–and, thus, a binary outcome–was deemed most clinically relevant. Supported by physiology and our own prior data,[3] breast symptoms typically peak on day 4 postprocedure or postdelivery. Therefore, our primary outcome was presence of breast symptoms on day 4.

The Bristol Breast Symptoms Inventory assesses the four domains of breast symptoms: engorgement, milk leakage, tenderness, and the need for pain relief modalities (scale: 1 reflects absence of symptoms; 2–4 reflect increasing degrees of symptoms).[7,13] Participants were classified as having an absence of breast symptoms, or asymptomatic, if they responded with a "1" in all four domains; otherwise, they were considered symptomatic. We also calculated a cumulative score for the Bristol Breast Symptoms Inventory by summing across its four domains.

We assessed bother from breast symptoms, side effects, and satisfaction using a Likert scale (scale range 0–6), with 0 being "not at all" and 6 being "extremely." We included side effects listed in the U.S. Food and Drug Administration drug package insert and allowed for free-text input.

In our prior trial that recruited participants at 18–28 weeks of gestation, 97.0% of those receiving placebo were symptomatic compared with 27.8% receiving cabergoline.[7] We anticipated that fewer people would be symptomatic earlier in the second trimester; therefore, we estimated that 30 participants in each gestational-age strata were required to show a 40% decrease in those reporting breast symptoms compared with those in the control group, with a power of 0.8 and an alpha of 0.049 (using O'Brien-Fleming rule for a planned interim analysis for primary outcome).[14] Given the paucity of data on frequency of breast symptoms in the early second trimester, the

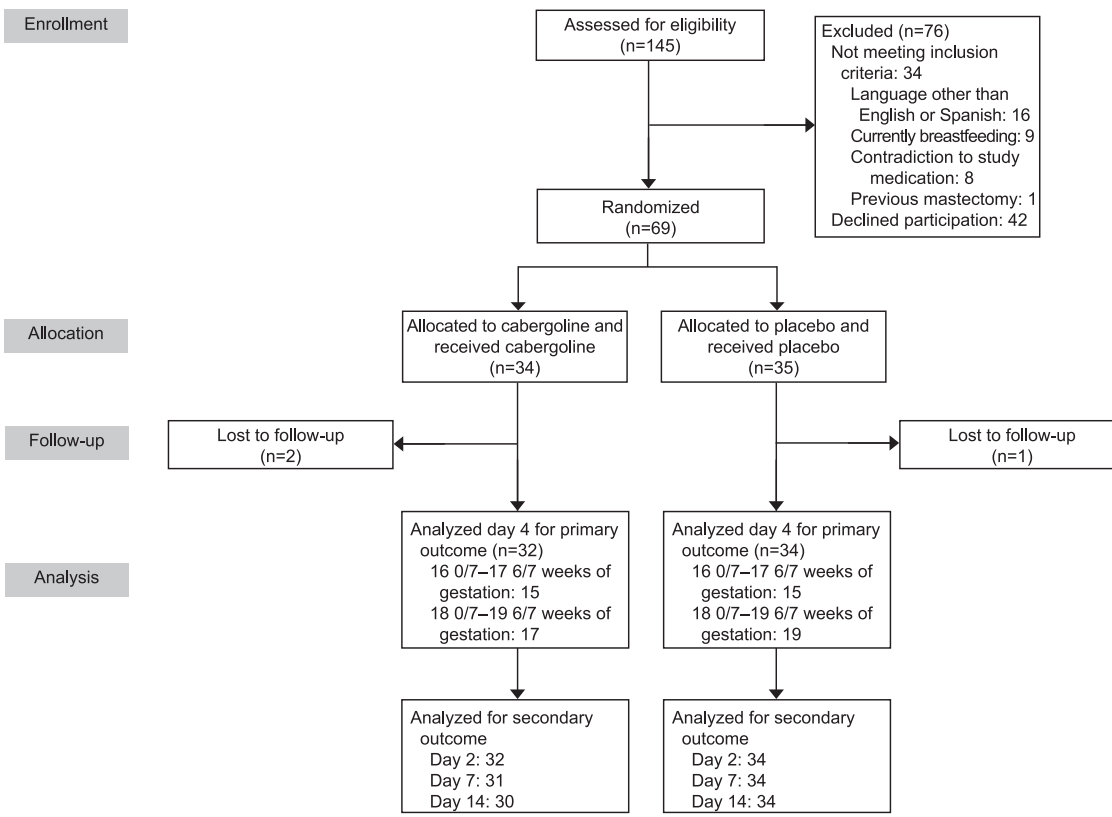

Fig. 1. CONSORT (Consolidated Standards of Reporting Trials) flow chart.
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interim analysis was planned with futility stopping rules. We planned to recruit a total of 72 individuals, anticipating 20% missing data and loss to follow-up. Because we powered the trial for each gestational-age strata, the pooled outcome would be powered to detect a 20% difference in presence of breast symptoms.

Data collected by RedCap surveys was exported to SAS OnDemand for Academics for analysis. We used a modified intention-to-treat for statistical analysis; we excluded patients lost to follow-up who did not return any survey data beyond baseline. In studies with low loss to follow-up, modified intention-to-treat is unlikely to bias statistical analysis.[15] We conducted a sensitivity analysis for missing data for our primary outcome to assess this assumption.

Baseline characteristics between the two groups were compared with a chi-squared test (categorical variables) and a *t* test (continuous variables). For our primary outcome (proportion with any breast symptoms), we used Fisher exact testing given high frequency of breast symptoms in the placebo group. Similarly, we also compared the two groups on the four domains of breast pain using Fisher exact testing. Given the nonparametric distribution of secondary outcomes, we compared the medians between groups with Wilcoxon rank sum test. To assess changes from baseline in the total Bristol Breast Symptoms Inventory score, we compared scores on days 2, 4, 7, and 14. A Bonferroni correction was applied to adjust for multiple comparisons, yielding an adjusted significance threshold of $P=.0125$.

RESULTS

From February 2024 through May 2025, we screened 145 patients for participation and enrolled 69 people (Fig. 1). We excluded three participants who did not provide additional data beyond enrollment from the analysis, for a final sample of 66 participants. The most common reasons for participants not meeting inclusion criteria were that they spoke a language other than English or Spanish or were currently breastfeeding an infant. We closed enrollment when we were powered for our primary outcome in both gestational duration strata given better than anticipated follow-up response rates.

Baseline demographics were balanced between groups; the median age was 27 years (range 18–45 years), median gestational duration was 18 weeks (range 16 0/7–19 6/7 weeks), 53.0% of the participants were nulliparous, 63.6% self-identified as Hispanic, and 68.2% had public insurance (Table 1). Most people sought abortion care for an undesired pregnancy (75.8%); fewer than 5% experienced fetal death. A majority (57.6%) were unaware that breast engorgement could occur in the early second trimester after their procedure.

At baseline, participants reported similar breast symptoms whether randomized to receive cabergoline or placebo (Fig. 2). On day 4, significantly fewer participants reported any breast symptoms (our primary outcome) in the cabergoline group compared with placebo (50.0% vs 88.2%, $P<.001$). This difference was significant in three of the four domains of breast symptoms: engorgement (25.0% vs 70.6%, $P<.001$),

Table 1. Demographic and Clinical Characteristics of Participants Randomized to Cabergoline or Placebo to Prevent Breast Pain After Early Second-Trimester Abortion or Pregnancy Loss

Characteristic	Cabergoline (n=32)	Placebo (n=34)
Age (y)	27.8±7.9	28.6±7.2
Parity	0 (0–5)	1 (0–6)
Nulliparous	19 (59.4)	16 (47.1)
Gestational duration (d)	126.7±8.3	127.7±8.2
Gestational duration (wk)		
16 0/7–17 6/7	15 (46.9)	15 (44.1)
18 0/7–19 6/0	17 (53.1)	19 (55.9)
Indication		
Undesired pregnancy	25 (78.1)	25 (73.5)
Fetal anomaly	5 (15.6)	8 (23.5)
Fetal death	2 (6.3)	1 (2.9)
Abortion method		
Procedural	30 (93.8)	33 (97.1)
Medication	2 (6.2)	1 (2.9)
Insurance		
Private	6 (18.8)	9 (26.5)
Medicaid	24 (75.0)	21 (61.8)
Self-pay	2 (6.3)	4 (11.8)
Gender*		
Woman	32 (100)	33 (97.1)
Nonbinary	0 (0)	1 (2.9)
Race*		
American Indian	0 (0)	1 (2.9)
Asian or Pacific Islander	3 (9.4)	3 (8.8)
Black	2 (6.3)	4 (11.8)
White	7 (21.9)	18 (52.9)
None of the above	2 (6.3)	2 (5.9)
No response	18 (56.3)	6 (17.6)
Ethnicity*		
Hispanic	23 (71.9)	19 (55.9)
Prior breast surgery	1 (3.1)	2 (5.9)
Prior breastfeeding	11 (34.4)	17 (50.0)

Data are mean±SD, median (range), or n (%). Percentages may not sum to 100% due to rounding.
* Self-identified.

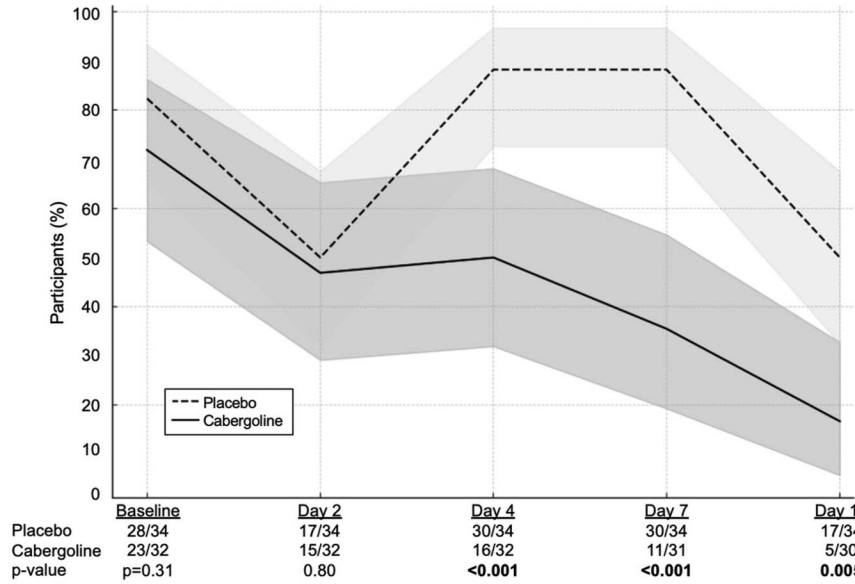

Fig. 2. Presence of breast symptoms experienced by participants randomized to cabergoline or placebo after early second-trimester abortion or pregnancy loss. Symptoms assessed by Bristol Breast Symptom Inventory. Data are percentage of total with 95% binomial CIs *shaded*. *P* values *bolded* to denote statistical significance.

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breast tenderness (40.6% vs 81.8%, *P*<.001), and the need for pharmacologic pain relief (6.3% vs 29.4%, *P*=.01). The proportion of individuals who reported any breast symptoms differed on days 4, 7, 14 (Fig. 2). The median change in the total Bristol Breast Symptoms Inventory score from baseline differed between the cabergoline and placebo groups on days 4 and 7 (Fig. 3).

Even separated by gestational duration strata, significantly fewer participants similarly reported any breast symptoms on day 4 in the cabergoline group compared with placebo (16 0/7–17 6/7 weeks: 46.7% vs 100%, *P*<.001; 18 0/7–19 6/7 weeks: 47.0% vs 78.9%, *P*=.046). Appendix 1, available online at http://links.lww.com/AOG/E445, presents gestational duration strata at each time point.

We conducted a worst-case sensitivity analysis by assuming that all participants lost to follow-up in the cabergoline group experienced breast symptoms, and none in the placebo group did. Under the worst-case

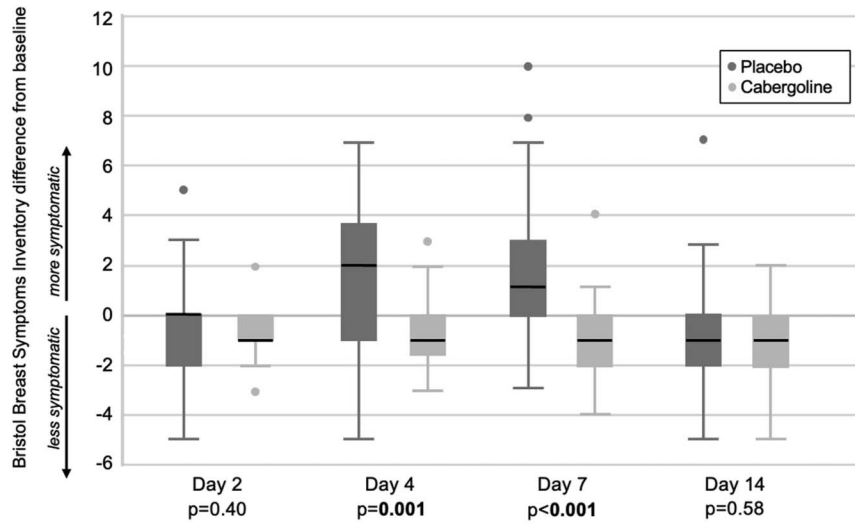

Fig. 3. Difference in Bristol Breast Symptom Inventory score from baseline reported by participants randomized to cabergoline or placebo after early second-trimester abortion or pregnancy loss. Symptoms assessed by Bristol Breast Symptom Inventory capture the four domains of breast symptoms: engorgement, milk leakage, tenderness, and need for pain relief modalities (scale: 1 reflects absence of symptoms; 2–4 reflect increasing degrees of symptoms). *Black horizontal line* denotes median difference from baseline. *Whiskers* denote the minimum and maximum observations within 1.5×interquartile range of quartile 1 and quartile 3. Observations outside this range are displayed as outliers. *Bolded P* values denote statistical significance.

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Table 2. Bother Associated With Breast Symptoms of Participants Randomized to Cabergoline or Placebo After Early Second-Trimester Abortion or Pregnancy Loss

Bother*	Cabergoline	Placebo	*P*
Baseline	n=32	n=34	
Bother rating	1 (0–3)	1 (0–6)	.54
Significant bother	0 (0)	1 (0.03)	1.0
Day 2	n=32	n=34	
Bother rating	1 (0–4)	1 (0–5)	.26
Significant bother	2 (6.3)	1 (2.9)	.61
Day 4	n=32	n=34	
Bother rating	1 (0–4)	3 (0–6)	**.01**
Significant bother	1 (3.1)	7 (20.6)	**.05**
Day 7	n=31	n=34	
Bother rating	0 (0–2)	1.5 (0–5)	**.01**
Significant bother	0 (0)	7 (20.6)	**.01**
Day 14	n=30	n=34	
Bother rating	0 (0–1)	0 (0–3)	**.001**
Significant bother	0 (0)	0 (0)	1.0

Data are median (range) or n (%).
Bold indicates statistical significance.
* Bother rating on Likert scale (range 0–6, with 0 being "not at all" and 6 being "extremely"); a rating of 4 or higher was considered significant bother.

scenario, the primary outcome of presence of breast symptoms on day 4 remains significantly different (cabergoline 52.9% vs placebo 85.7%, *P*=.003).

At baseline, the median bother rating from breast symptoms was 1 in both the cabergoline and placebo groups (*P*=.54) (Table 2). Patients allocated to placebo reported significantly higher median bother rating on days 4, 7, 14. On day 4, of patients randomized to cabergoline, 3.1% reported significant bother from breast symptoms compared with 20.6% randomized to placebo (*P*=.05).

The most common side effects in the 2 weeks after study medication allocation were headache (30.3%), fatigue (31.8%), and constipation (24.4%), and did not differ between groups (Table 3). More people who received cabergoline reported nausea or vomiting (34.4% vs 5.9%, *P*=.005); this difference between groups was most pronounced on day 7 (16.1% vs 0%, *P*=.02). The median bother from side effects did not differ by allocation at any time point (Appendix 2, available online at http://links.lww.com/AOG/E445). Most people were very satisfied

Table 3. Side Effects Reported by Participants Randomized to Cabergoline or Placebo After Early Second-Trimester Abortion or Pregnancy Loss

	No. of Participants With Side Effects		
	Cabergoline (n=32)	Placebo (n=34)	*P*
Headache	8 (25.0)	12 (35.3)	.36
Nausea and vomiting	11 (34.4)	2 (5.9)	**.005**
Fatigue	11 (34.4)	10 (29.4)	.67
Constipation	11 (34.4)	5 (14.7)	.06
Dizziness or lightheadedness	9 (28.1)	5 (14.7)	.18
Insomnia	6 (18.7)	8 (23.5)	.64
Hot flashes	5 (15.6)	8 (23.5)	.42
Anxiety	6 (18.8)	5 (14.7)	.66
Lower extremity edema	3 (9.4)	2 (5.9)	.67
Visual disturbance	3 (9.4)	2 (5.9)	.67
Palpitations	0 (0)	3 (8.8)	.24
Acid reflux	1 (3.1)	0 (0)	.48
Total reporting side-effects	26 (81.3)	31 (91.2)	.30

Data are n (%) unless otherwise specified.
Bold indicates statistical significance.

Authors' Data Sharing Statement

Will individual participant data be available (including data dictionaries)? *No.*

What data in particular will be shared? *Not applicable.*

What other documents will be available? *Not applicable.*

When will data be available (start and end dates)? *Not applicable.*

By what access criteria will data be shared (including with whom, for what types of analyses, and by what mechanism)? *Not applicable.*

with their allocation group (cabergoline 84.5% vs placebo 73.5%, P=.28).

DISCUSSION

This randomized trial demonstrates that a one-time dose of cabergoline is superior to placebo in preventing bothersome breast symptoms as early as 16 weeks of gestation after abortion or pregnancy loss.

Nearly all participants (88.2%) randomized to placebo experienced breast symptoms after early second-trimester abortion or pregnancy loss. This adds to a growing body of evidence describing the frequency and bother of breast engorgement after abortion care or management of fetal death in the second trimester.[3,16] Clinicians should be prepared to provide anticipatory guidance to patients that nearly all will experience bothersome breast symptoms and should provide anticipatory guidance and options, including evidence-based pharmacologic inhibition with cabergoline. In this trial, we recruited a mix of participants experiencing a pregnancy loss or seeking abortion care for a fetal anomaly or undesired pregnancy, suggesting people seeking uterine evacuation–regardless of indication for procedure–may be interested in a pharmacologic agent for lactation inhibition.

We found side effects to be, by self-report, common and mild for both patients receiving cabergoline and placebo. Significantly more people who received cabergoline reported nausea or vomiting compared with those allocated to placebo. Although nausea is a frequently reported side effect among patients taking daily doses of cabergoline,[17] we did not previously find a difference in frequency of nausea after a one-time dose in our prior trial.[7] Here, the primary driver of this finding comes from day 7 side effects. Although cabergoline is relatively long-acting, its half-life of only 65 hours increases the chance that this finding was due to type 1 error or even random error in sampling due to the lack of biological plausibility. Future meta-analysis may better quantify the frequency of side effects, because this is an important counseling point for patients choosing to take cabergoline.

We, again, selected a dose of 1 mg of cabergoline based on efficacy demonstrated after a full-term birth. One prior dose-finding study of people taking cabergoline for hyperprolactinemic disorders, not specific to recent pregnancy, randomized people to placebo (n=20) or cabergoline 0.125 mg (n=43), 0.5 mg (n=42), 0.75 mg (n=42), or 1.0 mg (n=41) twice weekly for 4 weeks. Prolactin levels normalized in 0%, 30%, 74%, 74% and 95% of participants, respectively, supporting a linear dose–response relationship for cabergoline in the treatment of hyperprolactinemia.[18] Because prolactin levels at the end of the third trimester are at least twice as high as in the second trimester, it is plausible that a lower dose of cabergoline (0.5 mg the formulation available in the United States.) still may be effective and is worthy of further investigation.

Strengths of this study include the randomized design and diverse participant population that used preferred-language questionnaires. We intentionally created a study team that includes breastfeeding medicine, maternal–fetal medicine, complex family planning, and lactation consultants to ensure that our outcomes are clinically relevant and patient-centered. The methodology was robust, with a power calculation and subsequent recruitment for the primary outcome in both gestational duration strata. The multisite recruitment with different patient populations–those presenting for hospital-based and clinic-based care–allows for broad generalizability of results.

One-third of people approached to enroll in the trial declined participation. Unfortunately, we did not collect information regarding why people declined trial enrollment. Because counseling increasingly includes the frequency and severity of breast symptoms second-trimester abortion or pregnancy loss, perhaps acceptance of a pharmacologic agent will increase. Importantly, not all people may want to inhibit lactation in this clinical setting–this is an important consideration as clinicians approach implementation. We were not powered to detect small but potentially clinically important differences in side effects. Finally, a potential limitation is that despite blinding, expectation bias among participants may have influenced reported outcomes.

We found cabergoline to be an effective, well-tolerated pharmacologic intervention to prevent bothersome breast symptoms after early second-trimester

abortion or loss. These findings support routine offering of cabergoline after abortion or pregnancy loss starting at 16 weeks of gestation.

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